

TELECONFERENCE MEETING OF THE
ADVISORY COMMITTEE ON THE
MEDICAL USES OF ISOTOPES

June 16, 2015

MEETING SUMMARY

PURPOSE

To discuss issues related to the implementation of the medical regulations in Title 10 Code of Federal Regulations (CFR) part 35, "Medical Use of Byproduct Material," including the training and experience requirements for authorized users of alpha and beta emitters and the Advisory Committee on the Medical Uses of Isotopes (ACMUI) subcommittee report on the revisions to the radioactive seed localization (RSL) licensing guidance.

OUTCOME

The U.S. Nuclear Regulatory Commission (NRC) staff gained a better understanding of the views and opinions of the ACMUI, as well as other stakeholders' views and opinions. The staff will consider these views in its continuing effort to make 10 CFR Part 35 more useful, practical, and not overly burdensome on licensees, while maintaining public health and safety. A full transcript and handout for the ACMUI teleconference meeting can be found on NRC's public website at <http://www.nrc.gov/reading-rm/doc-collections/acmui/meetings/>.

The draft ACMUI Subcommittee report on revisions to the Radioactive Seed Localization 10 CFR 35.1000 licensing guidance is available on NRC's public website under "ACMUI Subcommittee Reports": <http://www.nrc.gov/reading-rm/doc-collections/acmui/reports/>

AGENDA TOPIC

1. Discuss the Training and Experience Requirements for Authorized Users of Alpha and Beta Emitters
2. Discuss the ACMUI Subcommittee Report on the Revisions to the Radioactive Seed Localization Licensing Guidance

SUMMARY

Dr. Jennifer Cultrera discussed the need for the creation of a training and experience subcategory for authorized users (AUs) of intravenously-delivered oncology therapies supplied as patient-ready doses. She stated that the current requirements of 700 hours of training and experience and three proctored cases severely limits access to and discourages the use of these therapeutic radiopharmaceuticals. This proposed subcategory would require only 80 hours of training and experience for hematologists and oncologists seeking to administer low-risk alpha and beta-emitting radiopharmaceuticals.

The subcommittee provided a draft report for discussion with the full Committee. Subcommittee members included: Dr. Philip Alderson, Mr. Francis Costello, Dr. Ronald Ennis (chair), and Dr. Pat Zanzonico. The major sections under consideration by the subcommittee for revisions to the guidance included changes to the authorized user, written directive, and medical event

reporting. During the meeting, the subcommittee made the determination to further evaluate the RSL guidance, revise the draft report based on the discussion and provide a final draft for vote at the October 2015 ACMUI Meeting. The current RSL guidance can be found on the NRC's Medical Uses Licensee Toolkit at: <http://www.nrc.gov/materials/miau/med-use-toolkit.html>

RECOMMENDATIONS AND ACTIONS

Chair of the ACMUI, Dr. Thomadsen, created a subcommittee to evaluate if the required 700 hours for training and experience for authorized users of alpha and beta emitters places hardship on the patient community. If so, the subcommittee should make recommendations for potential changes (rulemaking). Subcommittee members include: Dr. Dilsizian, Dr. Ennis, Dr. Langhorst, Dr. Palestro (Chair), Ms. Weil, and Dr. Zanzonico. The subcommittee will present their draft report at the fall 2015 ACMUI Meeting scheduled to take place on October 8-9, 2015 at NRC Headquarters.

The ACMUI Radioactive Seed Localization Subcommittee will revise their draft report and will present the final draft report at the fall 2015 ACMUI Meeting.

Attachments:

List of Attendees

MEETING ATTENDEES

ACMUI

Bruce Thomadsen, Ph.D.	Chairman
Philip Alderson, M.D.	Vice Chairman
Francis Costello	Member
Vasken Dilsizian, M.D.	Member
Ronald Ennis, M.D.	Member
Susan Langhorst, Ph.D.	Member
Steven Mattmuller	Member
Michael O'Hara, Ph.D.	Member
Christopher Palestro, M.D.	Member
Laura Weil	Member
Pat Zanzonico, Ph.D.	Member

NRC

Josephine Piccone, Ph.D.	Director, Division of Materials Safety, States, Tribal and Rulemaking Programs (MSTR)
Pamela Henderson	Deputy Director, MSTR
Douglas Bollock	Branch Chief, Medical Safety and Events Assessment Branch (MSEB) and Designated Federal Officer
Sophie Holiday	Alternate Designated Federal Officer/ACMUI Coordinator
Michael Fuller	Medical Radiation Safety Team Leader
Maryann Abogunde	NMSS
Neelam Bhalla	NMSS
Marcia Carpentier	NMSS
Ashley Cockerham	NMSS
Jackie Cook	Region IV
Said Daibes, Ph.D.	NMSS
Gina Davis	NMSS
Sandra Gabriel, Ph.D.	NMSS
Robert Gallagher	Region I
Esther Houseman	NMSS
Donna-Beth Howe, Ph.D.	NMSS
Penny Lanzisera	Region I
Johari Moore	COMM/OCM
Jan Nguyen	Region I
Diane Render, Ph.D.	NMSS
Gretchen Rivera-Capella	NMSS
Michelle Smethers	NMSS
Tara Weidner	Region I

MEMBERS OF THE PUBLIC

Lee Allen	Spectrum Pharmaceuticals, Inc.
Ilham Almahamid	New York State Department of Health
Kathleen Brill	Foley Hoag LLP
Brian Carey	Foley Hoag LLP
Charles Coleman	Virginia Department of Health
Jennifer Cultrera	Florida Cancer Specialists & Research Institute
Robert Dansereau	New York State Department of Health
Al Dejesus	Spectrum Pharmaceuticals, Inc.
Hugh Evans	Eckert & Ziegler Radiopharma, Inc.
Nebeyou Fekadu	Cedar-Sinai Medical Center
Asfou Fenta	Virginia Department of Health
Karen Flanigan	New Jersey Department of Environmental Protection
Philip Griffin	Utah Division of Radiation Control
Michael Guastella	Council on Radionuclides and Radiopharmaceuticals (CORAR)
Georgia Hearn	American Society of Nuclear Cardiology (ASNC)
Amanda Johnsen	The Pennsylvania State University
Yungmi Kim	Spectrum Pharmaceuticals, Inc.
Caitlin Kubler	Society of Nuclear Medicine and Molecular Imaging (SNMMI)
Karen Langley	University of Utah
Angelique Lee-Rowley	Spectrum Pharmaceuticals, Inc.
Robin Levy	Lymphoma Cancer Foundation
Ralph Lieto	St. Joseph Mercy Health System
Gary Lunger	Bayer
Richard Martin	American Association of Physicists in Medicine (AAPM)
Gene Menendez	Spectrum Pharmaceuticals, Inc.
Mike Peters	American College of Radiology (ACR)
Andrea Ravard	Cedar Sinai Medical Center
Clarine Nardi Riddle	Kasowitz
Joseph Rodgers	Theragenics Corporation
James Schuh	CORAR
Karen Sheehan	Fox Chase Cancer Center
Michael Sheetz	University of Pittsburgh
Cindy Tomlinson	American Society for Radiation Oncology (ASTRO)
Jeffrey Vacirca	Community Oncology Alliance